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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/889,053

03/13/2003

Thomas Woods Keough

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06/21/2007

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EXAMINER

WHALEY, PABLO S

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

06/21/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/889,053		KEOUGH ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Pablo Whaley		1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 April 2007 and 01 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 8-10, 12, and 16 is/are pending in the application.
- 4a) Of the above claim(s) 8-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 12 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### *REQUEST FOR CONTINUED EXAMINATION*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/01/2007 has been entered.

Applicants' remarks, filed 04/03/2007, have been fully considered. The following rejections and/or objections are either withdrawn, maintained, or newly applied, as necessitated by amendment, for the reasons set forth below. They constitute the complete set presently being applied to the instant application.

### *CLAIMS UNDER EXAMINATION*

Claims 1, 2, 12, and 16 are herein under examination. Claims 3-7, 11, and 13-15 have been cancelled. This application contains claims 8-10 drawn to an invention nonelected with traverse in the response filed 11/14/2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### *PRIORITY*

Priority to US Provisional Application 60/116,502, filed 01/20/1999, has been acknowledged.

**CLAIM REJECTIONS - 35 USC § 112, 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 12, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims that depend directly or indirectly from claim 1 are also rejected due to said dependence.

Claim 1 now recites "providing a disulfonic acid or sulfonic acid covalently bonded to the N-terminus of said polypeptide" (step b), and "derivatizing said N-terminus of said polypeptide or said N-terminus of at least one peptide of said polypeptide with one or more disulfonic or sulfonic acids covalently bonded with the said polypeptide or peptide" (step c). As applicant has not set forth a limiting definition for the term "derivatizing", it is unclear whether applicant intends for "step c" to result in a peptide with multiple sulfonic acid groups at the N-terminus, a second 'derivatization' step, or something else. Clarification is requested via clearer claim language.

### **Obviousness-Type Double Patenting Rejection**

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321 (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

Claims 1, 2, 12, and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 4, 7, 8, and 9 of US Patent 7,074,570, as both share a common inventor (Youngquist). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the broadly encompassing scope of the instantly claimed invention causing the inventions to have overlapping embodiments. The instant claims and those of '570 recite the same method and sulfo-based reagents with minor variations. For example, claim 1 of the instant application recites derivatizing the N-terminus of a polypeptide using reagents of disulfonic or sulfonic acid, whereas '570 recites derivatizing the N-terminus of a polypeptide using sulfo moiety reagents coupled to an ester (claims 1 and 2). It would have been obvious to someone of ordinary skill in

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the art at the time of the instant invention to derivatizing the N-terminus of a polypeptide using other strong acids (i.e. sulfonic acid) known for thermal stability and resistance to reductive and oxidative cleavage. This is an obviousness-type double patenting rejection because the conflicting claims have in fact been patented.

### **CLAIM REJECTIONS - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 was rejected under 35 U.S.C. 102 (b) as being anticipated by Juhasz et al. (Proc. Nad. Acad. Sci. USA, 1994, Vol. 91, pp. 4333-4337), as set forth in previous office action mailed 01/03/2007.

Applicant's arguments, filed 4/3/2007, that Juhasz et al. do not teach covalent bonding of acidic reagents to improve ionization and detection of molecular weights of strongly acidic components is persuasive. This rejection is hereby withdrawn.

Claim 1 is rejected under 35 U.S.C. 102 (b) as being anticipated by Biemann et al. (US 5,607,859; Issued Mar. 4, 1997).

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Biemann et al. teach an improved method for determining the molecular weights of highly polyionic analytes using mass spectrometry [Abstract]. More specifically, Biemann et al. teach the following aspects of the instantly claimed invention :

- Providing at least one polypeptide, which implicitly contains at least one N-terminus [Col. 24, Example 4] and [Ref. Claim 3], as in claim 1.
- Providing R groups covalently linked to the amino acids may be derivatized to add highly ionic functional groups (i.e. highly acidic reagents) at the N-terminus [Col. 15, ¶ 4]
- Derivatization of peptides using polyacidic reagents to add sulfonate groups [Col. 15, lines 55-60] and polysulfonic acids [Col. 24, Example 4], as in claim 1.
- Spectrometric analysis using soft ionization techniques [Ref. Claim 1], which is an implicit teaching for MALDI and Electrospray mass spectrometry, as in claim 1.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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The following prior art publications are the basis for executing this rejection:

Claims 1, 2, and 16 are rejected under 35 U.S.C. 103(a) as being made obvious by Burlet et al. (RAPID COMMUNICATIONS IN MASS SPECTROMETRY, 1992, VOL. 6, p. 658-662), in view of Biemann et al. (US 5,607,859; Issued Mar. 4, 1997).

Burlet et al. teach methods for protonation of pre-charged derivatives for restoring favorable fragmentation properties [Abstract]. More specifically, Burlet et al. specifically teach experimental methods providing peptides, N-terminal derivatization of said peptides, and mass spectrometric analysis of said peptides [p.659, EXPERIMENTAL], as in claim 1. Furthermore, Burlet et al. teach the use of electrospray-tandem mass spectrometric analysis utilizing doubly protonated pre-cursors for analysis of tryptic digests [p.662, Col. 1, ¶ 2], as in claims 2 and 16.

Burlet et al. do not specifically teach the use of sulfonic acid covalently bound to polypeptides for derivatizing polypeptides, as in claim 1.

As set forth above, Biemann et al. provide methods for derivatizing peptides using polyacidic reagents to add sulfate or sulfonate groups [Col. 15, ¶4] or polysulfonic acids [Col. 24, Example 4], as in claim 1.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice charge promotion method of Burlet et al. using tags incorporating charged sulfonic acid, as taught by Biemann et al., as Burlet et al. clearly teach procedures that permit the introduction of charged (i.e. acidic) functional groups at either the N or C terminus [Results]. One of skill in the art would have been motivated to combine the above teachings in order to form highly sulfonated compounds that have increased sensitivity to MALDI analysis [Biemann et al., Example 4], resulting in the practice of the instantly claimed invention. One of



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ordinary skill in the art would have had a reasonable expectation of successfully combining the above teachings as both Burlet et al. and Biemann et al. teach methods directed to mass spectral analysis of peptides.

Claims 1, 2, and 16 are rejected under 35 U.S.C. 103(a) as being made obvious by Van Ness et al. (US 6,027,890; Filed July 22, 1997), in view of Spengler et al. (International Journal of Mass Spectrometry and Ion Process, 1997, Vol. 169/170, p.127-140).

Applicant's arguments, filed 4/3/2007, regarding Spengler et al. have been considered but are moot in view of the new grounds of rejection.

Van Ness et al. teach methods for enhancing the sensitivity in the analysis of biological-based assays [Abstract]. Van Ness et al. specifically teach methods for binding molecules of interest (including peptides) [Col. 36, lines 25-40] to detectable tags (i.e. derivatizing), which can carry a positive or negative charge under conditions of ionization in mass spectrometry (MS), and which include sulfonic acid as one of the preferred reagents [Col. 16, lines 25-47]. It is noted that as the applicant has not provided a limiting definition for "derivatizing" in the specification, the Examiner has broadly interpreted this term to mean "adding a functional group" for purposes of applying prior art. Van Ness et al. also teach connecting tags to molecules of interest through covalent interactions [Col. 31, lines 50-60], as in claim 1. Van Ness et al. also teach MALDI and electrospray ionization techniques for tag detection and spectral analysis [Col. 64, lines 1-25], as in claim 1. Van Ness et al. also teach examples of enzymatic cleavage of peptides [Col. 35, lines 30-35], as in claim 16.

Van Ness et al. do not specifically recite "derivatizing the N-terminus" of a polypeptide, as in claim 1, or the use of MALDI-PSD mass spectrometry, as in claim 2.

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Spengler et al. teach method of peptide sequencing of charged derivatives using both MALDI and MALDI-PSD [Abstract]. More specifically, Spengler et al. provide polypeptides comprising at least one N-terminus [Section 2.2.1], addition of acidic derivatizing agent to produce a derivatized analyte [Section 2.2.2, Fig. 1], and analyzing said derivatized analyte products using MALDI-PSD [Section 2.2.4] and [Fig. 5], as in claims 1 and 2.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the tag-based analysis method of Van Ness et al. using peptides derivatized at the N-terminus, as taught by Spengler et al., as peptide derivatization is well known to occur at the N-terminus [Spengler et al., Section 2.2]. One of skill in the art would have been motivated to combine the above teachings in order to improve fragmentation patterns using peptides derivatized at the N-terminus and analyzed using MALDI-PSD [Section 3.3], resulting in the practice of the instantly claimed invention. One of ordinary skill in the art would have had a reasonable expectation of successfully combining the above teachings as both Van Ness et al. and Spengler et al. teach methods directed to mass spectral analysis of peptides.

### CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

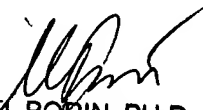
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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